safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2010, through September 30, 2010. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2010, THROUGH SEPTEMBER 30, 2010

PMA No. Docket No.	Applicant	Trade name	Approval date
P080027, FDA–2010–M–0402	OraSure Technologies, Inc	ORAQUICK HCV RAPID ANTIBODY TEST.	June 25, 2010.
P050034, FDA–2010–M–0361	Vision Care Ophthalmic Technologies, Ltd.	IMPLANTABLE MINIATURE TELESCOPE.	July 1, 2010.
P080026, FDA–2010–M–0519	Abbott Molecular, Inc	ABBOTT REALTIME HBV ASSAY	August 13, 2010.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: November 18, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–29731 Filed 11–24–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3229–N]

Medicare Program; Quality Improvement Organization (QIO) Contracts: Solicitation of Proposals From In-State QIOs—Idaho, Maine, South Carolina, and Vermont

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice fulfills the Secretary's obligation under section 1153(i) of the Social Security Act (the Act) to provide at least 6 months' advance notice of the expiration dates of contracts with out-of-State Quality Improvement Organizations (QIOs) before renewing any of those QIOs' contracts. It also specifies the period of time in which in-State QIOs may submit a proposal for those contracts.

DATES: Interested organizations may submit a proposal to perform the QIO work in any of the States listed in this announcement. The request for proposal (RFP) will be made available to all interested organizations through the Federal Business Opportunities (*http://www.fedbizopps.gov*) Web site. CMS anticipates that the RFP for the QIO contracts will be released sometime during the month of February 2011. Interested organizations should monitor the Federal Business Opportunities Web site for all information relating to the RFP.

ADDRESSES: Proposals for the contracts must be submitted to the Centers for Medicare & Medicaid Services, Acquisitions and Grants Groups, OAGM, Attn.: Naomi Haney-Ceresa, 7500 Security Boulevard, Mail Stop C2–21–15, Baltimore, Maryland 21244–1850.

FOR FURTHER INFORMATION CONTACT: Alfreda Staton, (410) 786–4194.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (title I, subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97–248) amended Part B of title XI of the Act (the Act) by establishing the Utilization and Quality Control Peer Review Organization program.

Utilization and Quality Control Peer Review Organizations, now known as Quality Improvement Organizations (QIOs), currently review certain health care services furnished under title XVIII of the Social Security Act (the Act) (Medicare) to determine whether those services are reasonable, medically necessary, provided in the appropriate setting, and are of a quality that meets professionally recognized standards. QIO activities are a part of the Health Care Quality Improvement Program (HCQIP), a program that supports our mission to ensure health care quality for our beneficiaries. The HCQIP rests on the belief that a plan's, provider's, or practitioner's own internal quality management system is key to good performance. The HCQIP is carried out locally by the QIO in each State. Under the HCQIP, QIOs provide critical tools (for example, quality indicators and information) for plans, providers, and practitioners to improve the quality of care provided to Medicare beneficiaries. The Congress created the QIO program in part to redirect, simplify, and enhance the cost-effectiveness and efficiency of the peer review process.

In June 1984, we began awarding contracts to QIOs. We currently maintain 53 QIO contracts with organizations that provide medical review activities for the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands. The organizations that are eligible to contract as QIOs have satisfactorily demonstrated that they are either physician-sponsored or physician-access organizations in accordance with section 1152 of the Act and our regulations at 42 CFR 475.102 and 475.103. A physician-sponsored organization is one that is both composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the respective review area and who are representative of the physicians practicing in the review area. A physician-access organization is one that has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to ensure adequate peer review of the services furnished by the various medical specialties and subspecialties. In addition, a QIO cannot be a health care facility, health care facility association, a health care facility affiliate, or in most cases a payor organization. (The regulations provide that, in the event CMS determines no otherwise qualified non-payor organization is available to undertake a given QIO contract, CMS may select a payor organization which otherwise meets certain requirements to be eligible to conduct Utilization and Quality Control Peer Review as specified in Part B of Title XI of the Act and its implementing regulations.) Section 1152(2) of the Act requires QIOs to perform review functions in an

efficient and effective manner, and perform reviews of quality of care in an area of medical practice where actual performance is measured against objective criteria, which defines acceptable and adequate practice. The selected organization must have a consumer representative on its governing board.

The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) amended section 1153 of the Act by adding paragraph (i). This provision prohibits CMS from renewing the contract of any QIO that is not an in-State QIO without first publishing in the **Federal Register** a notice announcing when the contract will expire. This notice must be published no later than 6 months before the date the contract expires and must specify the period of time during which an in-State organization may submit a proposal for the QIO contract for that State. If one or more qualified in-State organizations submit a proposal for the QIO contract within the specified period of time, we cannot automatically renew the current contract on a noncompetitive basis, but must instead provide for competition for the contract in the same manner used for a new contract under section 1153(b) of the Act. An in-State QIO is defined under section 1153(i)(3) of the Act as a QIO that has its primary place of business in the State in which review will be conducted (or, be a subsidiary of a parent corporation, whose headquarters is located in that State).

There are currently 4 QIO contracts with entities that do not meet the statutory definition of an in-State QIO. The areas affected for purposes of this notice along with the respective contract expiration dates are as follows:

Vermont—July 31, 2011
Maine—July 31, 2011
Idaho—July 31, 2011
South Carolina—July 31, 2011

II. Provisions of the Notice

This notice announces the scheduled expiration dates of the current contracts between CMS and the out-of-State QIOs responsible for review in the areas mentioned above.

Interested in-State organizations may submit a proposal in competing to become the QIO for these States. In order to be eligible for contract award, the organization must have its primary place of business in the States in which review will be conducted or be a subsidiary of a parent corporation, whose headquarters is located in that State. In order to be eligible for contract award, each interested organization must further demonstrate that it meets the following requirements:

A. Be Either a Physician-Sponsored or a Physician-Access Organization

1. Physician-Sponsored Organization

a. The organization must be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, who are representative of the physicians practicing in the review area.

b. The organization must not be a health care facility, health care facility association, health care facility affiliate, or payor organization. However, statutes and regulations provide that, in the event CMS determines no otherwise qualified non-payor organization is available to undertake a given QIO contract, CMS may select a payor organization which otherwise meets requirements to be eligible to conduct Utilization and Quality Control Peer Review as specified in Part B of Title XI of the Act and its implementing regulations.

c. In order to meet the "substantial number of doctors of medicine and osteopathy" requirements as specified above in paragraph A.1.a, an organization must state and have documentation in its files showing that it is composed of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area. In order to meet the representation requirements as specified above in paragraph A.1.a, an organization must state and have documentation in its files demonstrating that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area. Alternatively, if the organization does not demonstrate that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, the organization must demonstrate in its proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

2. Physician-Access Organization

a. The organization must have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to ensure adequate peer review of the services furnished by the various medical specialties and subspecialties.

b. The organization must not be a health care facility, health care facility association, health care facility affiliate, or payor organization.

c. An organization meets the requirements specified above in paragraph A.2.a., if it demonstrates that it has available to it at least one physician in every generally recognized specialty and has an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

B. Have at Least One Individual Who Is a Representative of Consumers on Its Governing Board

If one or more organizations meet the above requirements in a QIO area and submit proposals for the contracts in accordance with this notice, we will consider those organizations to be potential sources for the 4 contracts upon their expiration. These organizations will be entitled to participate in a full and open competition for the QIO contract to perform the QIO statement of work.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: October 28, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2010–28817 Filed 11–24–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Ethics Subcommittee (ES)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the CDC announces the following meeting of the aforementioned subcommittee:

Time and Date: 2 p.m.—3:30 p.m. Eastern Standard Time, January 4, 2011.

Place: Teleconference.

Status: Open to the public, limited only by availability of telephone ports. The public is welcome to participate during the public comment period. A public comment period is tentatively scheduled from 3 p.m.—3:15 p.m. To participate in the teleconference, please dial 1–877–928–1204 and enter conference code 4305992.

Purpose: The ES will provide counsel to the ACD, CDC, regarding a broad range of public health ethics questions and issues arising from programs, scientists and practitioners.